ATTACHMENT A

IN THE CLAIMS:

1. (Original) A pharmaceutical composition suitable for topical administration comprising:

about 1 to about 30% by weight of an α-hydroxy acid or a pharmaceutically acceptable salt thereof having a purity of at least 90% and a concentration of degradation product(s) less than about 10% of the starting concentration of said α-hydroxy acid;

about 0.05 to about 2.0% by weight of prednicarbate or a pharmaceutically acceptable salt thereof having a purity of at least 90% and a concentration of degradation product(s) less than about 10% of the starting concentration of said prednicarbate; and

about 0.5 to about 10% by weight of a pyrrolidone carboxylate salt.

2. (Original) The pharmaceutical composition of claim 1, comprising about 1 to about 10% by weight of said α-hydroxy acid, about 0.1 to about 1.0% by weight of said prednicarbate, and about 1 to about 8% by weight of said pyrrolidone carboxylate salt.

3. (Original) The pharmaceutical composition of claim 2,

comprising about 3 to about 7% by weight of said α-hydroxy acid, about 0.15 to about 0.5% by weight of said prednicarbate, and about 3 to about 7% by weight of said pyrrolidone carboxylate salt.

4. (Original) The pharmaceutical composition of claim 1, wherein said α-hydroxy acid is present in said composition as an acid or salt.

5. (Original) The pharmaceutical composition of claim 1, wherein said α-hydroxy acid is present in said composition as mixture of an acid and a salt.

6. (Original) The pharmaceutical composition of claim 1, wherein said α-hydroxy acid is selected from the group consisting of atrolactic acid, benzilic acid, 4-chloromandelic acid, citric acid, 3,4-dihydroxymandelic acid, ethyl pyruvate, galacturonic acid, gluconolactone, glucuronic acid, glucuronolactone, glycolic acid, 2-hydroxybutanoic acid, 2-hydroxypentanoic acid, 2-hydroxyhexanoic acid, 2-hydroxyheptanoic acid, 2-hydroxyactanoic acid, 2-hydroxynonanoic acid, 2-hydroxydecanoic acid,2-hydroxyundecanoic acid, 4-hydroxymandelic acid, 3-hydroxy-4-methoxymandelic acid, 4-hydroxy-3-methoxymandelic acid, α-hydroxyarachidonic acid, α-

hydroxybutyric acid, α-hydroxyisobutyric acid, α-hydroxylauric acid, α-hydroxymyristic acid, α-hydroxypalmitic acid, α-hydroxystearic acid, 3-(2'-hydroxyphenyl)lactic acid, 3-(4'-hydroxyphenyl)lactic acid, lactic acid, malic acid, mandelic acid, methyllactic acid, methylpyruvate, mucic acid, α-phenylactic acid, α-phenylpyruvic acid, pyruvic acid, saccharic acid, tartaric acid, tartronic acid, pharmaceutically acceptable salts thereof, and mixtures thereof.

7. (Original) The pharmaceutical composition of claim 6, wherein said α-hydroxy acid is lactic acid or a pharmaceutically acceptable salt thereof.

8. (Original) The pharmaceutical composition of claim 1, wherein said pyrrolidone carboxylate salt is sodium pyrrolidone carboxylate.

9. (Original) The pharmaceutical composition of claim 1, wherein said composition has a pH of about 3.0 to about 6.0.

10. (Original) The pharmaceutical composition of claim 9, wherein said composition has a pH of about 4.0 to about 5.0.

11. (Original) The pharmaceutical composition of claim 1,

wherein said composition is an emulsion having an oil phase and an aqueous phase.

12. (Original) The pharmaceutical composition of claim 11, wherein said oil phase comprises an oily material selected from the group consisting of mineral oil, petrolatum, petroleum derivatives, fatty acids, fatty acid derivatives, fatty alcohols, fatty alcohol derivatives, paraffins, and mixtures thereof.

13. (Original) The pharmaceutical composition of claim 11, wherein said emulsion is formed using an emulsifier selected from the group consisting of polyoxyethylene sorbitan fatty acid esters, sorbitan fatty acid esters, propylene glycol stearate, glyceryl monostearate, polyethylene glycol, fatty alcohols, polymeric ethylene oxide-propylene oxide block polymers, derivatives thereof, pharmaceutically acceptable salts thereof, and mixtures thereof.

14. (Original) The pharmaceutical composition of claim 13, wherein said emulsifier is a combination of stearyl alcohol and polyoxyethylene(20) cetostearyl ether, and glyceryl stearate and polyethyleneglycol-100/glyceryl stearate.

15. (Original) The pharmaceutical composition of claim 13, wherein said emulsion is formed with an emulsifier that is either naturally or synthetically prepared.

16. (Original) The pharmaceutical composition of claim 11, wherein said oil phase contains at least two emulsifiers.

17. (Original) The pharmaceutical composition of claim 1, wherein said α-hydroxy acid and said pyrrolidone carboxylate salt are present in said aqueous phase.

18. (Original) The pharmaceutical composition of claim 17, wherein said prednicarbate is dispersed in the emulsion.

19. (Original) The pharmaceutical composition of claim 1, wherein said composition further comprises about 50 to about 98% by weight of water.

20. (Original) The pharmaceutical composition of claim 1, further comprising an additional excipient selected from the group consisting of antioxidants, chelates, preservatives, emollients, humectants, fluid alkyl alcohols, thickening agents, pH modifier, and mixtures thereof.

21. (Original) The pharmaceutical composition of claim 20, wherein said pH modifier is selected from the group consisting of an acid, base, and mixtures thereof.

22. (Original) The pharmaceutical composition of claim 20, wherein said pH modifier has a hydroxyl group.

23. (Original) The pharmaceutical composition of claim 22, wherein said pH modifier is sodium hydroxide.

24. (Original) The pharmaceutical composition of claim 1, wherein said composition is in a lotion, cream, ointment, shampoo, or other pharmaceutically acceptable topical dosage form.

25. (Original) The pharmaceutical composition of claim 1, wherein said composition is placed in a suitable containment vessel comprising a product contact surface composed of a material selected from the group consisting of glass, plastic, steel, stainless steel, aluminum, Teflon, polymeric structure, ceramic structure, alloys, and mixtures thereof.

26. (Original) The pharmaceutical composition of claim 25, wherein said composition is placed in said suitable containment

vessel to facilitate manufacturing, handling, processing, packaging, storage, and administration of said composition.

27. (Original) A method of treating a steroid responsive dermatosis in a mammal, comprising topically administering to a mammal in need thereof a therapeutically effective amount of a pharmaceutical composition suitable for topical administration comprising:

about 1 to about 30% by weight of an α-hydroxy acid or a pharmaceutically acceptable salt thereof having a purity of at least 90% and a concentration of degradation product(s) less than about 10% of the starting concentration of said α-hydroxy acid;

about 0.05 to about 2.0% by weight of prednicarbate or a pharmaceutically acceptable salt thereof having a purity of at least 90% and a concentration of degradation product(s) less than about 10% of the starting concentration of said prednicarbate; and

about 0.5 to about 10% by weight of a pyrrolidone carboxylate salt.

28. (Original) The method of claim 27, wherein said steroid responsive dermatosis has a cause selected from the group consisting of hypersensitivity, IgE mediation, anti-membrane

antibody, immune complex disease, cell mediated immunity, and combinations thereof.

29. (Original) The method of claim 27, wherein said steroid responsive dermatosis is caused by an insult to a tissue of said mammal, wherein said insult is selected from the group consisting of a physical insult, a chemical insult, an environmental insult, and combinations thereof.

30. (Original) The method of claim 29, wherein said insult is a topical or internally mediated insult.

31. (Original) The method of claim 27, wherein said steroid responsive dermatosis is a secondary physiologic response to a primary disease.

32. (Original) The method of claim 31, wherein said primary disease is selected from the group consisting of an infection, an allergic response, a hyperproliferative disorder, an immunologic disorder, a metabolic disorder, a drug induced response, a disorder related to proper or improper organ function, and combinations thereof.

33. (Original) The method of claim 27, wherein said steroid

responsive dermatosis produces a symptom in said mammal selected from the group consisting of inflammation, redness, tissue disruption, tissue deformation, exudates, crusting, pain, pruritis, and mixtures thereof.

34. (Original) The method of claim 27, wherein said steroid responsive dermatosis is selected from the group consisting of contact dermatitis, eczema, atopic dermatitis, ichthyosis, psoriasis, xeroderma, seborrheic dermatitis, nummular dermatitis, stasis dermatitis, lichen simplex chronicus, dermatophytids, candidiasis, scabies, pityriasis rosea, lichen planus, pityriasis rubra pilaris, bullous pemphigoid, miliaria, acute and chronic eczema, lupus erythematosis, photoallergic reactions, pruritis, and combinations thereof.

35. (Original) The method of claim 27, wherein the composition is formulated for pediatric use.

36. (Original) The method of claim 27, wherein the composition is administered to sensitive skin.

37. (Original) A method of treating diseased tissue in a mammal, comprising topically administering to said diseased tissue a therapeutically effective amount of a pharmaceutical

composition suitable for topical administration comprising:

about 1 to about 30% by weight of an α-hydroxy acid or a pharmaceutically acceptable salt thereof having a purity of at least 90% and a concentration of degradation product(s) less than about 10% of the starting concentration of said α-hydroxy acid;

about 0.05 to about 2.0% by weight of prednicarbate or a pharmaceutically acceptable salt thereof having a purity of at least 90% and a concentration of degradation product(s) less than about 10% of the starting concentration of said prednicarbate; and

about 0.5 to about 10% by weight of a pyrrolidone carboxylate salt.

38. (Canceled)

39. (Canceled)

40. (Canceled)

41. (Canceled)

42. (Canceled)

43. (Canceled)

44. (Canceled)

45. (Canceled)

46. (Canceled)

47. (Canceled)

48. (Canceled)

49. (Original) A pharmaceutical composition suitable for topical administration comprising an emulsion comprising:

an oil phase comprising an oily material selected from the group consisting of mineral oil, petrolatum, petroleum derivatives, fatty acids, fatty acid derivatives, fatty alcohols, fatty alcohol derivatives, paraffins, and mixtures thereof and at least two emulsifiers;

an aqueous phase comprising about 1 to about 10% by weight of an α-hydroxy acid or a pharmaceutically acceptable salt thereof having a purity of at least 90% and a concentration of degradation product(s) less than about 10% of the starting concentration of said α-hydroxy acid and about 1 to about 8% by

weight of a pyrrolidone carboxylate salt; and

about 0.1 to about 1.0% by weight of prednicarbate or a pharmaceutically acceptable salt thereof having a purity of at least 90% and a concentration of degradation product(s) less than about 10% of the starting concentration of said prednicarbate dispersed throughout said emulsion,

wherein said pharmaceutical composition has a pH of from about 3.0 to about 6.0.

50. (Canceled)

51. (Canceled)

52. (Canceled)

53. (Canceled)

54. (Canceled)

55. (Canceled)

56. (Canceled)

57. (Canceled)

58. (Canceled)

59. (Canceled)

60. (Canceled)

61. (Canceled)

62. (Canceled)

63. (Canceled)

64. (Currently Amended) A method of treating a steroid responsive dermatosis in a mammal, comprising administering to a mammal in need thereof a therapeutically effective amount of ~~a~~ the pharmaceutical composition suitable for topical administration of claim 49 ~~comprising an emulsion comprising:~~

~~an oil phase comprising an oily material selected from the group consisting of mineral oil, petrolatum, petroleum derivatives, fatty acids, fatty acid derivatives, fatty alcohols, fatty alcohol derivatives, paraffins, and mixtures thereof and at least two emulsifiers;~~

~~an aqueous phase comprising about 1 to about 10% by weight~~

~~of an α hydroxy acid or a pharmaceutically acceptable salt thereof having a purity of at least 90% and a concentration of degradation product(s) less than about 10% of the starting concentration of said α hydroxy acid and about 1 to about 8% by weight of a pyrrolidone carboxylate salt; and~~

~~about 0.1 to about 1.0% by weight of prednicarbate or a pharmaceutically acceptable salt thereof having a purity of at least 90% and a concentration of degradation product(s) less than about 10% of the starting concentration of said prednicarbate dispersed throughout said emulsion,~~

~~wherein said pharmaceutical composition has a pH of from about 3.0 to about 6.0~~.

65. (Currently Amended) A method of treating diseased tissue in a mammal, comprising topically administering to said diseases tissue a therapeutically effective amount of ~~a~~ the pharmaceutical composition suitable for topical administration of claim 49 ~~comprising an emulsion comprising:~~

~~an oil phase comprising an oily material selected from the group consisting of mineral oil, petrolatum, petroleum derivatives, fatty acids, fatty acid derivatives, fatty alcohols, fatty alcohol derivatives, paraffins, and mixtures thereof and at least two emulsifiers;~~

~~an aqueous phase comprising about 1 to about 10% by weight~~

~~of an α hydroxy acid or a pharmaceutically acceptable salt thereof having a purity of at least 90% and a concentration of degradation product(s) less than about 10% of the starting concentration of said α hydroxy acid and about 1 to about 8% by weight of a pyrrolidone carboxylate salt; and~~

~~about 0.1 to about 1.0% by weight of prednicarbate or a pharmaceutically acceptable salt thereof having a purity of at least 90% and a concentration of degradation product(s) less than about 10% of the starting concentration of said prednicarbate dispersed throughout said emulsion,~~

~~wherein said pharmaceutical composition has a pH of from about 3.0 to about 6.0~~.

66. (Canceled)

67. (Canceled)

68. (Original) A process for preparing a pharmaceutical composition suitable for topical administration comprising an emulsion, said process comprising:

1) preparing an oil phase comprising an oily material selected from the group consisting of mineral oil, petrolatum, petroleum derivatives, fatty acids, fatty acid derivatives, fatty alcohols, fatty alcohol

derivatives, paraffins, and mixtures thereof and at least two emulsifiers;

2) preparing an aqueous phase comprising an α-hydroxy acid or a pharmaceutically acceptable salt thereof having a purity of at least 90% and a concentration of degradation product(s) less than about 10% of the starting concentration of said α-hydroxy acid and a pyrrolidone carboxylate salt;

3) adjusting the pH of said aqueous phase to a range of about 3.0 to about 6.0.

4) adding said oil phase to said aqueous phase while mixing at a temperature of about 55 to about 85 ^{0}C to obtain a homogenous emulsion;

5) cooling said emulsion to a temperature of about 25 to about 45 ^{0}C;

6) solubilizing prednicarbate or a pharmaceutically acceptable salt thereof having a purity of at least 90% and a concentration of degradation product(s) less than about 10% of the starting concentration of said prednicarbate in a lower alkyl alcohol and dispersing said prednicarbate throughout said emulsion; and

7) recovering a topical emulsion pharmaceutical composition.

69. (Original) The process of claim 68, wherein said oil

phrase is prepared by mixing said oily material and said at least two emulsifiers at a temperature of about 55 to about 85 ^{0}C.

70. (Original) The process of claim 69, wherein said oil phase is prepared by further mixing a thickening agent, an emollient, and a preservative with said oily material and said at least two emulsifiers.

71. (Original) The process of claim 70, wherein said aqueous phase is prepared by first mixing a preservative followed by a polymer thickening agent in purified water at a temperature of about 55 to about 85 ^{0}C before adding said α-hydroxy acid and said pyrrolidone carboxylate salt.

72. (Canceled)

73. (Canceled)

74. (Original) The process of claim 68, wherein said pH is adjusted by adding sodium hydroxide to said aqueous phase.

75. (Original) The process of claim 68, wherein said pH is adjusted to a range of from about 4.0 to about 5.0.

76. (Canceled)

77. (Original) A pharmaceutical composition produced according to the process of claim 68, wherein the α-hydroxy acid and the prednicarbate in said composition each maintain a purity of at least 90% and a concentration of degradation product(s) less than about 10% of the starting concentration of the α-hydroxy acid and the prednicarbate.

78. (Original) The pharmaceutical composition of claim 77, wherein said composition exhibits chemical and physical stability suitable for topical administration.

79. (Original) A pharmaceutical composition suitable for topical administration comprising:

about 1 to about 30% by weight of lactic acid or a pharmaceutically acceptable salt thereof;

about 0.05 to about 2.0% by weight of prednicarbate or a pharmaceutically acceptable salt thereof; and

about 0.5 to about 10% by weight of sodium pyrrolidone carboxylate.